ORIGINAL

TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON

THE FDA MODERNIZATION ACT OF 1997 [FDAMA]

SECTION 406(b)

Pages 1 thru 95

Bethesda, Maryland
September 14, 1998

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
Washington, D.C. 20002
(202) 546-6666

98N-0339

TR 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON

THE FDA MODERNIZATION ACT OF 1997 [FDAMA]

SECTION 406(b)

MONDAY, SEPTEMBER 14, 1998

9:00 a.m. to 11:55 a.m.

Bethesda Holiday Inn

Bethesda, Maryland 20814

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
Washington, D.C. 20002
(202) 546-6666

A G E N D A

P R O C E E D I N G S

MS. SUDYAM: Good morning and welcome to the last of FDA's official stakeholder meetings. We are very pleased to have all of you here with us today, and we have a very busy agenda. But before we begin, I would like to start by giving you some information about why we are here.

Most of you know that Section 406(b) requires that FDA consult with its appropriate stakeholders, and we have been in thep rocess of doing this since early this summer. We have had very successful meetings so far to date, and we are looking forward to the kind of information that we had from the other meetings coming forward today as well. So we are looking forward to an exciting, interesting time.

I do have some additional information that I would like to give you to put it in context of why we are here. The first is FDAMA has a number of themes; the FDA Modernization Act, and I think it's important to reflect on those themes as we think about the themes of what our stakeholders are telling us in these meetings.

I would suggest that the interactive development, timely action, patient access, codifying the re-engineering activities of the Agency, accountability, the discretion versus criteria and then, in fact, a strong emphasis on international harmonization are all things that we have had heard from stakeholders as being important to them as well.

FDA has also been over the last five years in a resource crunch. And this chart will show you the FDA resource picture from 1993 through 1999. If you will notice, it looks from the visible, that FDA's resources have grown significantly in that six-year time period.

I think when you look at that chart you will also see, however, that FDA's base resources have been shrinking over that time period, and while we have received additional resources for the Prescription Drug User Fee Act, for the Mammography Quality Standards Act and for some special initiatives, such as the Food Safety Initiative and Tobacco, FDA's base resources are basically staying the same. In addition, FDA has not been adequately compensated for the inflation costs that have happened over the last six years.

The next chart. This chart shows it in an even greater way. The base, which is the yellow, shows the resource level going down and, in addition to that, the workload of the Agency has gone up, and so there is, in fact, an unfunded workload mandate that the Agency has been forced to absorb in the base resources of this Agency.

In the meetings that we have had to date, there have been some consistent themes that we have heard from stakeholders, and those consistent themes are that our stakeholders of all kinds want to have open, transparent processes, so that they know and can expect what is going to

happen from the FDA. They also want more and better communication. They want to hear from us more frequently, and they want to have that communication more direct, concise, and in a variety of formats.

They want us to continue the management efficiencies that we have started through the re-engineering efforts, and they want those management efficiencies to continue to reap resources so that we can, in fact, move forward with the increasing workload.

They also have reflected a need for adequate agency funding. This has been a consistent theme throughout all of our meetings; that they believe the FDA needs to have an adequate base-funded resources, and they want to be available to help and to partner. We have had offers of help from professional associations, from consumer groups, from industry trade associations, and we think that those are all possible partnerships that we can take advantage of in the future.

We would like to also have your comments in writing, and I want to remind you that the FDA Modernization Act has a docket number. We would like to hear from people to this docket. You can send your comments to the docket in three different ways. You can send your comments by mail, you can send your comments by e-mail, and you can send your comments on-line via the Web.

So, today, we are here to hear from groups who, perhaps, some of them we have heard from before, but they have a different message for us today, and we have a very distinguished FDA panel who will be joining me in the front to listen to these groups as they make their presentations.

We are not here as a part of this panel to debate. We are here to listen and to ask clarifying questions. So I would hope that we would have some interaction with the panelists, and we are also going to have an open mike at the end of the meeting, so that people who have not signed up to speak can also speak.

So if I could, I would like to introduce the FDA panel. Our panelists are going to include Mr. Robert Byrd, who is the Deputy Commissioner for Management and Systems; Ms. Sharon Smith Holston, who is the Deputy Commissioner for External Affairs; Mr. Willaim Schultz, who is the Deputy Commissioner for Policy; Mr. Dan Michels, who is the Director of the Office of Communications and the Office of Regulatory Affairs; and Mr. Bern Schwetz, who is the Interim Chief Scientist and also Director of the National Center for Toxicological Research.

In addition, we have some FDA resources who will be in the audience, and I expect that if we have a question that this distinguished panel can't answer, we will call on some of these specific resource people from each of the

centers. We have Mr. Bert Mitchell, who is the Associate Director for Policy and Regulation for the Center for Vetrinary Medicine; we have Dr. Katherine Zoon, who is the Director of the Center of Biologics; we have Deborah Henderson, who is the Director of Executive Operations for the Center for Drugs; we have Dr. Loreka Joseph, who is the Director of the Office of Health and Industry Programs for the Center of Devices and Radiological Health; we have Juanita Yates, who is the Acting Director for Consumer Operations in the Center for Food Safety; and we have Mr. Stephen Goldman, who is the Associate Director for Medicine for MedWatch in the Office of External Affairs.

We are looking forward to an interesting time, and I would ask now that our panel would join us. I will introduce each of the people as they speak. And so if our two panels could please join us at the front, we would appreciate it.

Our first speaker this morning is Mr. Carl Dixon, who is President and Executive Director of the Kidney Cancer Association.

MR. DIXON: Do you want us to speak from here or there?

MS. SUDYAM: It's entirely your choice.

MR. DIXON: Good morning. I am Carl Dixon, the President and Executive Director of the Kidney Cancer

Association. I would like to start by thanking the Agency for having this meeting. The Kidney Cancer Association wishes to commend it for holding a public discussion of its objectives and functions, and the Association is very engaged with the Agency, and my comments are based on our firsthand experience.

Some general comments to begin. Presently, cancer therapies and diagnostics are reviewed by the FDA in a variety of different divisions and centers. For example, while therapies for breast cancer are reviewed in the Division of Oncology, drug products, hormone therapies for prostate cancer are reviewed by an entirely different division; the Division of Reproductive and Neurologic Drug Products, which does not have an oncology focus.

In addition, cancer biologic and drug therapies are reviewed by two entirely different FDA centers. The Kidney Cancer Association believes that the FDA should take immediate steps to consolidate the review and approval of cancer therapies and diagnostics into one central division or office.

In 1996, the FDA's Oncology Drug Advisory Committee, in a letter to Dr. Friedman, requested that portions of CBER and CDER that deal with cancer therapeutics be merged for the efficiency and effectiveness of cancer drug development. The Agency should heed this request.

Recently, the FDA proposed merging the Office of Special Health Issues with the much larger Office of Consumer Affairs. This proposed merger was widely disapproved by the constituents of the Office of Special Health Issues and was withdrawn. We believe the Agency should use the Office of Special Health Issues, an office that works very effectively with patient and consumers as a model for all of itso activities. It should see to it that the FDA's consumer corsortium becomes a more effective vehicle for choosing consumers to serve on advisory committees.

The public's understanding of drug development is very poor. The average American has very little awareness of the FDA's role in this process. The FDA needs to fully integrate the public into its business. It needs to put money into educating the public. In return, the public needs to convince both the Congress and the Executive Branch to provide adequate funding to support the vast public education that needs to be done about drug development and the regulation of that development.

Many believe that the FDA public meetings and FDA center meetings are little more than shams. The Agency must commit the resources necessary to make these meaningful. It must accept that the patient community has a substantive role as the public's representative with the Agency. Many

feel that the public is, at best, tolerated by the Agency. For example, the way to give real public notice of meetings is not just to publish it in the Federal Register.

Our input and comments, especially anecdotal facts, are provided for in the Agency's rules. But, in fact, they are sometimes derided by staff. If this is only a perception, it is one strengthened because the public is always scheduled to speak before the data is presented at advisory committee meetings. How can we comment in an informed way? Hearing the patient's comments first assures that they appear unorganized and uninformed.

The FDA does not belong to the staff of the FDA. It belongs to the people of this country. The FDA staff must be trained to welcome the public. The public, by the way, is not the members of the Drug Review Committees. The FDA's public includes patients who benefit from the drugs, and the representatives of the drug industry who develop the drugs.

A specific comment to conclude. FDA must focus its attention on its primary purpose, reviewing new drug applications and ensuring that drugs are safe and effective. It should not seek to enlarge its mission. In furtherance of its mission, the Agency should delegate appropriate tasks to other third parties. It should conserve its resources. The Agency needs to seek out opportunities to improve its

efficiency through cooperative partnerships.

As I recently stated in a letter to the editor of USA Today, the FDA sets worldclass standards for the safety and effectiveness of new medicines. I expect it to continue to do so. Thank you.

MS. SUDYAM: Thank you, Mr. Dixon. Members of the FDA panel, are there any questions at this time for Mr. Dixon, any clarifying comments?

Ms. Holston?

MS. HOLSTON: Carl, I appreciate the positive remarks about the Office of Special Health Issues, but you also said that you thought we should make the consumer consortium a more effective vehicle for selecting public participants on our advisory committees. I would appreciate if you could just expand a little bit on the concerns you have about the way in which the consortium operates.

MR. DIXON: Well, I think the way the consortium operates is not well understood by the appropriate communities and the stakeholders. I think the selection and involvement process is far from transparent, and we would encourage a lot more input and discussion about how these important appointments are made and the criteria.

MS. HOLSTON: Thank you.

MS. SUDYAM: Other comments from the panel?

[No response.]

MS. SUDYAM: Thank you.

Our next speaker is Mr. Joshua Javits, who is Trustee of the ALS Association. Mr. Javits?

MR. JAVITS: Thank you very much. I would just like to speak from here, if that's all right.

My name is Josh Javits, and I serve as a member of the Board of Trustees of the Amyotrophic Lateral Sclerosis Association, and I would like to thank you for the opportunity to speak today about how implementation of the FDA Modernization Act can have a positive effect on people who are living with ALS.

I am also the son of someone who had ALS, the late Jacob Javits, who served this country very proudly for 24 years in the U.S. Senate and for eight years as a member of the House of Representatives. My father died in 1986, after a real struggle with ALS, which is, as you know, a degenerative and always-fatal disease. While in Washington, and later in private life, he led a very full life and maintained a busy schedule, giving speeches, writing articles, even after being diagnosed with ALS in 1980.

As the disease progressed, he required life support, including a respirator and a wheelchair and eventually became virtually paralyzed. He died within five years of diagnosis. The usual period is about three to four years from onset to death and approximately 30,000 Americans

have ALS today. Another 300,000 living Americans will die of the disease unless effective treatments or cure is found.

We in the ALS community believe that the highest priority for all FDA centers, particular CDER and CBER, is to expedite the development and review of therapies for treating serious and rapidly fatal diseases like ALS. Drugs and biologic products for ALS must be managed on fast tracks. Therefore, the FDA guidelines must be explicit regrading fast-track diseases.

The FDA should solicit from AMA sections and other medical professional organizations recommendations for properties for fast-track diseases. Current Guideline Section 112 of the FDA Modernization Act is not adequately explicit, particularly on ALS. Therefore, we await anxiously the Agency's release of a guideline for document for this section.

Efficacy thresholds for approval of ALS drugs should be set within the context of the time urgency that this disease presents. When he was FDA Commissioner, Dr. Kessler stated some years ago, "When dealing with serious and life-threatening conditions, we cannot wait for all of the evidence to come in." For life-threatening illnesses, such as ALS, the FDA can expedite the availability of therapies to patients in desperate need by providing greater authority to approve drugs that strongly suggest

effectiveness, even at a modest level.

The FDA should consider efficacy relative to safety and approval of safe, even modestly effective drugs ensures ALS patients have at least a chance. Many cancer drugs and immunosuppressive drugs for organ transplantation are approved based on efficacy relative to safety. ALS has not been treated by the FDA the same as other life-threatening conditions.

We are encouraged and hopeful that proper implementation of the fast-track therapies will increase and expedite the availability of new drugs for ALS, as history has done for AIDS and cancer.

The participation of ALS experts on the Scientific Advisory Panel is imperative, not only explicitly required by law, but from a practical standpoint, it is absolutely critical that true experts be represented on panels of the actual diseases under review.

The current forum of public comment at open Scientific Advisory Panel meetings is extremely important. However, patients who have made the effort to participate have sometimes left with the feeling that the panel members had made their decisions prior to the hearing and prior to their testimony and, therefore, they felt that they had little or no influence.

The FDA and the Scientific Advisory Panel should,

therefore, explore ways to improve the effectiveness, openness, opportunity for dialogue with the public, as well as the panel's receptiveness to what they hear.

Furthermore, the FDA should aggressively educate patient advocacy groups, disease-specific organizations, disease experts, and new biotech companies that have never filed their product with the FDA about FDA functions, processes, and scope.

Understanding the challenge it presents to scientific design, review and analysis, we ask that the FDA work with the pharmaceutical industry to design trials that will allow patients to participate in more than one clinical trial and will minimize the use of placebos. We stress the importance of the expanded access program and encourage FDA to continue to make this program an option for ALS patients without requiring data collection.

I greatly appreciate this opportunity to present our views and thank you very much for your attention.

MS. SUDYAM: Thank you for your comments. Are there any questions for Mr. Javits from the FDA panel?

[No response.]

MS. SUDYAM: Our next speaker is Robin Harrison, Director of the Diabetes Consumer Cooperative.

[No response.]

MS. SUDYAM: I assume then Robin Harrison not

here. Our next speaker is Millicent Gorham, Executive Director of the National Black Nurses Association and member of the FDA Consumer Consortium.

MS. GORHAM: Thank you very much and good morning. The National Black Nurses Association is pleased to submit testimony before the Food and Drug Administration regarding the FDA Modernization Act.

The National Black Nurses Association is a professional organization of registered nurses, licensed vocational practical nurses, and nursing students. Our mission is to investigate, define, and determine the health care needs of African Americans and to implement changes to make available health care commensurate with that of the larger society.

Our association represents 150,000 African American nurses and has 27 years of commitment and dedication to quality health care for all Americans. On behalf of our membership and all those we represent, NBNA thanks the Food and Drug Administration for providing us with the opportunity to state our position on issues under its jurisdiction.

NBNA applauds the work of the Congress and FDA for pushing through legislation that would allow FDA to approve drugs in a speedy manner, yet be able to maintain the safety and efficacy of the consumers' health. The African American

community continues to strive for positive health outcomes with the understanding that access to the appropriate drugs and new technology will help to change the downward spiral health indices.

While cancer morbidity and mortality rates may be on the down swing overall, breast cancer rates and prostate cancer rates in the African American community remains high. HIV-AIDS rates in African American women are now at near epidemic proportion, and cardiovascular disease remains the number one killer for all African Americans. Speedy access to new, safe, and effective drugs and technology may make the difference in the quality of life in our communities.

Access to health care services, particularly making sure that the appropriate pharmaceuticals are accessible in managed care organizations' formularies is germane to improving the health care of African Americans and the underserved. It is believed that managed care organizations in underserved communities have not always provided access to premiere pharmaceuticals that would enhance the health care of consumers. Too often, more advanced drugs are not a part of the managed care formulary, making it difficult for the health care provider to manage a patient's health, particularly a patient with multiple chronic health care needs.

It is evident that our nation must be able to

bring safe drugs to the marketplace, and our nation must offer to all consumers appropriate, culturally sensitive information about those drugs. Critical to bringing a drug application for FDA approval is the need for appropriate clinical trials. Research has shown that drugs react very differently between the sexes and the races. More research must be conducted by culturally competent research scientists within the ethnic minority community to ensure that the drugs that FDA approves will result in positive health outcomes for African Americans.

Access to the most up-to-date health care technology is key to improving the health care status in the African American community. One new technology recently approved by FDA to better detect cervical cancer may help to improve the overall survival rates for African American women. This technology, the next-generation pap smear, offers genuine hope to all women to better evaluate cervical cells in a more efficacious manner.

While we find that FDA does its job by providing thorough scientific review to approve drugs and new technology, there appears to be a gap between the FDA approval process and the HCFA coverage process. HCFA has suggested that it no longer wants to accept FDA approval of drugs as its primary coverage criteria. This will slow down substantially the dissemination of new drug therapies.

Moreover, in some cases, HCFA reimbursement rates for new technologies are so low that it places barriers to women being able to access technologically advanced health care services.

NBNA recommends that FDA and HCFA work hand in hand to make sure that FDA-approved drugs and technology are covered and have appropriate reimbursement levels so the American consumer may have access to these health care services in a timely manner.

The consumer community applauds the FDA and its Office of Consumer Affairs for excellent performance in the area of public participation considering their staff and resource limitations. It is time that the Agency re-evaluates how it conducts its public participation process. As a member of the FDA consumer consortium that recommends consumer representatives to the Agency's 16 panels and 32 advisory committees, there needs to be more funding provided to adequately staff and manage the public participation process.

It is quite an involved process to recruit and maintain a database of consumer representatives to serve on the FDA panels and advisory committees, to provide the necessary training and support that the consumer representative is comfortable with the FDA review process and to manage the public participation process.

NBNA recommends that FDA dedicate adequate staffing and resources to manage the FDA consumer consortium process and support of consumer representatives and public members who serve on the FDA advisory committees and panels.

We need to make sure that the consumer voice is heard during the public policy deliberations on new drugs and new technology. Perhaps a public hearing to solicit public comment is in order for this issue. We stand ready to lend our suggestions and ideas.

Thank you very much.

MS. SUDYAM: Thank you, Ms. Gorham. Now I would like to ask if the FDA panel has any questions for Ms. Gorham.

Dr. Schwetz?

DR. SCHWETZ: Your comments about racial basis for differences in sensitivity is focused primarily on drugs. Would you also extend that to other things that we are worried about like food additives and food substances or is your focus primarily on drugs?

MS. GORHAM: The focus is primarily on drugs and new technology.

MS. SUDYAM: OIther comments or questions?

[No response.]

MS. SUDYAM: Our next speaker is David Nelson, who is the Senior Director for Special Initiatives of the

National Mental Health Association.

MR. NELSON: Good morning. My name is Dave Nelson with the National Mental Health Association. Before I begin, I want to echo what Millicent said about access to more advanced medications in the drug formulary. That has been one of our primary advocacy concerns. However, that is not what I came to speak about this morning, but we do want to lend our support to what she was saying.

The National Mental Health Association's advocacy tends to focus on the public sector working with Medicaid, also around mental health parity. Talking about the modernization of the FDA is somewhat new to us, but we are happy to be here this morning. What I want to talk about today, priamrily, though focuses on access to information for mental health consumers, access directly from the pharmaceutical company.

The National Mental Health Association was founded in the beginning of this century by a mental health consumer, Clifford Beers, and 90 years later we have gone on to be the nation's largest and oldest stakeholder mental health organization. With approximately 340 mental health associations across the country, we take a lead role in advocacy, in public education, in services, and in supporting research.

As an organization representing mental health

stakeholders, representing family members, and primarily consumers themselves, we have a vital interest in maximizing the availability and clarity of information available to mental health consumers concerning new products and services.

What I want to basically say this morning is that what has happened to the mental health consumer movement mirrors what has happened to the consumer movement in general health care and, except in rare exceptions, should be treated no differently.

The mental health consumer movement has mirrored the growth and the sophistication of the broader health consumer movement in this country. Today, people with mental health needs are often educated consumers able to ask questions, evaluate information, and make choices concerning the treatment options that are available to them. However, historically, the medical community has resisted direct-to-consumer advising of prescription medicines and chosen to tightly control the type of information that is conveyed to consumers.

Traditionally, mental health consumers have been locked out of the information loop regarding the medications that are available to them and alternatives to what they have been prescribed.

With the growing sophistication of the mental

health consumer movement, the growing sophistication of the consumer health movement overall, consumers can increasingly play an important role in partnering with clinicians to select appropriate medications and other services.

Sound medical practice should support people with mental health needs as informed consumers and serve to educate them about the benefits and potential side-effects of the products in question. Generally speaking, the more information available to consumers, the greater the role the mental health consumer will take in the clinical decisions that affect them. These consumers are often keenly aware of the medications that work or fail to work for them. As consumers are educated and informed about the products being offered to them, they have an increased ability to work with clinicians and develop appropriate treatment plans.

If done appropriately, direct-to-consumer advertising enhances consumer knowledge about available treatemnts. Although part of the information conveyed must provide essential details about the side-effects and other concerns related to the product, in general, direct-to-consumer advertising enhances knowledge about illnesses and treatments. It facilitates increased consumer knowledge and a dialogue between the consumer and the clinician.

If consumers are aware of their own drug history and the drugs being offered to them, such a dialogue can

often result in the clinician selecting a different medication than would have initially been prescribed. Such advertising can also serve a public education purpose, encouraging people to seek out screening and treatment for mental illnesses they might have otherwise denied themselves.

It clearly makes sense to the National Mental Health Association for this information to be presented directly to consumers to include details about major side-effects. But these details should be presented in a way that encourages the flow of information. For example, we would expect to see information about major health risks and ways to learn about more information through 800 numbers and Internet sites.

However, it is not NMHA's intention, at this juncture here today, to discuss specific regulations and implementation regarding this type of information. As an association of mental health stakeholders, we want to convey the importance of including mental health stakeholders, specifically consumers themselves, in the development of guidelines and future discussions and would like to play a role in making sure that direct primary consumers were at these discussions in the future.

We also want to promote policies that bring as much information as possible to their disposal. Maximizing

the availability and clarity of inforamtion for mental health consumers concerning these products, offers the same benefits as it does to other health consumers.

Mental health consumers are actively seeking such information about illnesses and available medications. Pharmaceutical companies can be one important source of information and should be able to communicate information about the treatment that is available, but they are not alone in the provision of this information. Organizations such as ours, offer a wide range of resources for information regarding illnesses and the treatment options that are available, including medications, but also alternative sources of treatment and community-based services.

Through our national, state, and local networks, we would provide additional resources to help consumers educate themselves and develop treatment plans in partnership with clinicians.

We encourage companies working to increase the flow of information about their products to work with us, the National Mental Health Association, and other consumer-based organizations in developing presentations that adequately meet the needs of consumers, as they make their choices.

Information must have a reasonable level of reader

friendliness and be consistent with the cultural diversity of a population served. For example, it's important that information be conveyed in the languages and cultures that are appropriate to each community.

Although forums and panels such as this present an excellent first step in the process, there can be no substitute for ongoing input from primary consumers in each market--input in FDA discussions such as this--and with each pharmaceutical company, with each advertising campaign, the consumers need to play a primary role.

We encourage organizations to make use of focus groups and other vehicles that offer mental health consumers a chance to put input concerning the type of information that is being conveyed to them. Such tools could also help address potential problems with misleading advertising and overpromotion.

NHMA looks forward to being a partner with the FDA and other groups in the audience as they work to make these connections. We do, however, defer to clinicians and consumers themselves in the development of specific guidelines regarding the type of information and the way that it can be conveyed as we work to increase the flow of information to consumers.

In general, however, such information clearly supports the empowerment of consumers as they work to be

partners in their own treatment options.

Thank you very much.

MS. SUDYAM: Thank you, Mr. Nelson. Is there anyone on the panel who has a question? Mr. Schultz?

MR. SCHULTZ: I have a couple of questions I would like to ask the whole panel, if I may.

The first one is Mr. Nelson made some very interesting comments about direct advertising to consumer, and I was wondering whether either of the other members of the panel have any views on that.

MS. GRIFFITH: My name is Diane Griffith, and I represent the National Breast Implant Support and Information Groups. And for quite some time we have been concerned about advertising that we felt was false and misleading, and we have expressed our concerns. So I don't know what the Agency's overview on overseeing advertising is. I don't know if it's your job or the FTC's. I'm really not sure.

MR. SCHULTZ: For prescription drugs, it is FDA.

There's another question I want to ask, which was raised by some of the discussion. We, obviously, have limited resources, as you saw in the opening presentation. One of the kinds of things that we have to weigh is the issue of whether we should, when we have a choice, be putting resources into approving products or reviewing them

and making decisions when the applications come into us versus putting resources into helping companies design studies and working with them to develop protocols and helping them very early in the stage of product development.

I was wondering whether any of the members of the panel have any views on how we should allocate our resources and make those choices.

MS. GORHAM: Thank you. I think it's really important that you do both. I really hate to give a one or the other and try to make some kind of a balance.

We found that, particularly in the research, particularly with African Americans, particularly with women, that it is time that there be more women as part of those clinical trials and helping and more African Americans and other people of other races to be a part of those clinical trials. It's important, if we are going to improve the health care indices of all of these ethnic minority communities, as well as between the sexes, that you do help them find ways of conducting the studies, that there will be treatments that will help to improve the health care status of everyone.

MS. SUDYAM: Other comments on that question?

MR. NELSON: But it's not normal role of our advocacy. Those seem important. I am going to defer to other folks who have been involved in those type of debates

in the past.

MR. SCHULTZ: Let me ask another question. We have responsibility, obviously, to review drug applications for new drugs, particularly the break-through drugs that deal with serious and life-threatening diseases that all of you are so concerned with. We also have some limited responsibility with regard to drug prices in the sense that we are responsible for reviewing applications to market generic drugs, which interject competition and which patients are also concerned about, particularly those patients who are concerned about drug prices.

Does anybody on the panel have any view as to how we ought to weigh those responsibilities and allocate resources to those two activities?

MR. GORHAM: I guess the only thing I can say about that is that we just want to make sure that whatever position that you take, in terms of pricing the drugs, that the drugs are priced in such a way that the managed care organizations will put those drugs in a formulary. That is really key for everyone to be able to access those drugs. If they are only providing the generic drugs in the formulary, in some cases, if those generic drugs are not the same as the original drug or if there is any deviation, then there is a deviation in terms of the level of effectiveness of that drug.

So it's a major concern to make sure that the pricing is appropriate for all of the drugs, so that they can be placed in those formularies.

MR. NELSON: Similar comments with us. We have cases of individuals being put on generic drugs that they know do not work for them within formularies, you know, my work is specifically within the Medicaid formulary in each state. We're putting in fail-twice policies, where the consumer must actually fail twice before they can get off the formulary and receive the more advanced medication. With our case, we know what failure means. We are talking about hospitalization. And going off of that drug that works for them could have long-term effects, rather than just short-term effects.

So keeping those priced within a range that can be affordable within the formulary is, of course, important to us. However, most of our advocacy has been working with state offices to make sure that those drugs are included in the formulary, not so much addressing the price issue.

MR. SCHULTZ: Thank you.

MS. SUDYAM: Thank you. Our last speaker for this panel is Ms. Diane Griffith, who is the Congressional Liaison for the Breast Implant National Support Organization.

MS. GRIFFITH: Thank you for this opportunity,

panel members, ladies and gentlemen. Time and areas of my expertise limit my remarks to just three of the six objectives of the Modernization Act. I will address No. 2, maximizing the availability and clarity of information for consumers and patients concerning new products, and 6, eliminating backlogs in the review of applications and submissions. I will address No. 8, regarding crosscutting issues; that is, educating consumers and health professionals on risk and risk avoidance behavior. I will offer my views on Questions 3, 4, 5, and 6.

As for No. 2, regarding clarity of information, this obligation should include old products. I recommend that a point person be designated to accept, seek, and research data for consideration, review, and its dissemination among consumers, academic experts, advocacy groups, and health care professionals with regard to old and new products, and including an 800 telephone number designation.

As for No. 6, common sense dictates that not all products, drugs, and devices are equal. There will be applications and reviews that are too complicated to fit one template. The public's safety should be the first priority. Will the Agency ever again be so overpowered and demoralized by political and industry influence or its resources and enforcement powers so diminished that the Agency would hide

product injury data in the Federal Register or other obscure media, withholding information from the medical community and the public?

Why would the Agency compromise and trade its reputation and public health mission, reputation, and profit protection of industry as it did in June of 1988 by private publication without public warning? Consumers will never again be so naive as to believe that industry will be forthcoming in divulging any negative product information.

Moving on to crosscutting issues, No. 8, educating consumers and health professionals. In the past, conscientious FDA scientists have made recommendations to issue recommendations that were overruled by higher-ups. I recommend that an independent, unbiased panel be available for independent recommendation without prejudice against the scientist.

My suggestion for Questions 3, 4, 5, and 6 follows: As the victim of a grievous FDA regulatory fiasco, I am extremely fearful of dismantling the present review-research process, without a proven, viable alternative. I deeply represent and find morally indefensible any plan or program that would exploit the FDA mission for business opportunities by Underwriter's Laboratory, the American Society for Testing Materials, or the Health Industry Manufacturer's Association. It is repugnant to me that any

measure of the FDA mission be diluted by greed. I oppose testing and review conducted by third parties.

My suggestion for Question 4 would be that the Agency include consumer advocacy groups in its list of collaborators. You will be amazed by the impact of their sympathy, encouragement, and humanity. You will find our experience and insight valuable.

My suggestion for Question 5, regarding nonregulatory approaches, was stated in my August 18th remarks at the FDA conference. I state, again, that it's essential for the FDA Office for Women to be provided with the funding and empowerment to develop an expanded outreach program. It would be beneficial if the outreach program worked in cooperation with advocacy groups. In this office, instituted to serve women's health issues, they can best accumulate and make available information for consumers, particularly on adverse event injury report.

I have previously stated that as technology and new product development advances to increased demands on the Agency, the Office for Women will surely experience the need of a larger contributions to public health education.

I strongly suggest, also, that the Agency charge medical professionals, such as the Plastic Surgeons, for the buckets and tons of breast implant brochures they order to promote the sale of augmentation mammoplasty. These

brochures have turned into an instrument of promotion because they still do not give an accurate presentation of FDA risk data.

My suggestion for Question 6, regarding the FDA gold-standard seal on foods, drugs, biologicals, and medical devices: I do believe these benchmarks should be earned, and the Agency could charge user fees for those who qualify and wish to use this seal as a method of product promotion.

However, in the same manner, I request the FDA require a skull and crossbone seal to be prominantly displayed on Class III experimental devices, which still have not satisfied FDA requirements of proof of device safety.

In closing, I have one more suggestion for the FDA. As a severely injured breast implant recipient, who has lost access to fair judicial process, health care, the right to work, and who has been dependent on food stamps, welfare, social security disability, as do many other breast implant recipients, I have lost faith in the FDA as a competent and dependable regulatory agency.

An FDA public apology for judgment lapse in managing the breast implant crisis might be in order. It would not negate the damage done to so many women and their families, but might begin to rebuild and restore the public trust in the Agency.

My hope is that the FDA will be led by dedicated activists and advocates for science, not politics, in the 21st Century. Thank you.

MS. SUDYAM: Thank you, Ms. Griffith. Panel members, are there any questions for MS. Griffith?

MR. SCHULTZ: The Agency has been so criticized on how it's handled breast implants from people with all different perspectives, a whole range. I would just be interested in hearing more from you as to what you--

MS. GRIFFITH: Well, we feel the Agency is culpable for the manufacturers, bottom line, and could have and should have done more, and should havel asked questions earlier. You have got two million women out here. It wouldn't hurt to say, "I'm sorry."

MS. SUDYAM: Mr. Byrd, do you have a question?

MR. BYRD: It wasn't so much a question, as an observation. I think that, as we have heard from the panelists here this morning, I can certainly continue to see some of the themes that you mentioned earlier, Linda--the theme for more resources, the themes that we do as much as we can to manage our resources as efficiently as we can. We hear both of those things, and we hear many more.

As Ms. Sudyam indicated earlier, we are in an environment of constrained resources and in an environment of constrained resources, it's very important that we

prioritize our initiatives. It is also important that we leverage our resources as much as we can and do all we can to achieve operational efficiencies. We have done a lot of that. We are continuing to look at ways to leverage resources to get more resources other than to the appropriations process. We are looking at those ways, but we are also thinking strategically within the Agency.

As we prioritize resources and prioritize the direction that the Agency is going to take and doing that prioritization we must do that over a number of years, and I would like to encourage the panelists not to lose faith with the Agency because some of their concerns of resources might not be addressed the first year.

But having the stakeholders' engagement and involvement in helping the Agency prioritize its resources, it's essential, and I would just like to thank the panelists and encourage them to continue in that direction.

MS. SUDYAM: Thank you. Ms. Holston?

MS. HOLSTON: Ms. Griffith, you said that you were just unalterably opposed to third-party review and then you cited certain organizations.

MS. GRIFFITH: Right. I just don't want anybody--we don't trust industry. We want you folks to do the science.

MS. HOLSTON: If there were any possibility of

having objective, third-party scientific organizations to whom, perhaps, sponsors might, for instance, pay a fee to have products reviewed or something like that and then those results reviewed by the Agency, are you saying that there is no circumstance under which a third party could be trusted with assuming some of the responsibilities?

MS. GRIFFITH: I would have to know what the criteria is for the third party. It just makes us very anxious and very uncomfortable because we are so distrustful of industry. I mean, it's not just breast implants. I mean, there are other things I could cite, you know. We just want you folks to be on top of everything, and run everything, and be unbiased, and have all of the support, the science support in the world. I can only tell you what the other women tell me.

We just wish you had more money. If we had our way, we'd go get it for you.

MS. SUDYAM: Well, thank you. Thank you for that endorsement. We appreciate that.

Is there, at this point in time, anyone in the audience who might have a question or a comment related to this particular panel? If so, now might be the time to come and address the group.

MS. GORHAM: I have one other comment, if I can.

MS. SUDYAM: Yes, please.

MS. GORHAM: The gentleman asked me about food additives. One of the things that I have been--the Office of Consumer Affairs has been most helpful to our organization, and they have come to our annual conference. They are going to be writing an article for us on food safety. And so we appreciate the initiative, the food safety initiative, and look forward to receiving additional information, as it pertains to those food additives in the food and how they might impact our health.

MS. SUDYAM: Thank you.

MS. LOCKE: Hi. I'm Rosemary Locke with Why Me National Breast Cancer Organization.

Breast cancer is a complex illness, and women need access to a broad range of therapies to treat breast cancer. Most recently, for example, I testified on approval for Herseptin for women with metastatic disease. Obviously, the panel addressed the risk and benefits associated with that drug and many of the therapies we have to deal with, and I think advocates are grateful to FDA for being included to the extent that we have. We also thank you because it's been an education process for the advocacy community in understanding the complexities that you deal with and the trade-offs on risks and benefits.

I would also want to pick up on what Carl Dixon was saying about the Cancer Liaison Office. That's a very

important office for the cancer community. Because of the complexity of the issues that you deal with at FDA, it's often very difficult for us to find the right individuals dealing with these drugs and devices. Sometimes one part of the FDA does not always know what another part of the FDA is doing on a related issue and, often, that Office of Cancer Liaison has been the contact person to help us sort through who we need to talk to at FDA.

So, again, thank you for your openness in including us in this process.

MS. SUDYAM: Thank you. Thank you for your comments.

Ms. Griffith?

MS. GRIFFITH: I just wanted to say that's why I suggested having a point person for hot issues. It would make things easier for everyone, I think.

MS. SUDYAM: If there are no other questions for this panel, I would like to thank all of our speakers for the time they put into the thoughtful remarks that they presented to us. I would like to just sort of highlight what I think are some of the important points that we heard, which I think do, in fact, reinforce some of the themes that we've heard from some of our other stakeholder meetings.

I think we heard about the importance of public participation and how important it is for our public

meetings, our advisory committees, and our consortium process to be more effective. Even though it is effective to an extent now, we need to reach out more. We need to continue to make our processes more open, transparent and receptive. We need to make sure that we have better qualified and specific consumer representatives who can represent advocacy positions to our advisory panels.

I think we also heard that we need more information to help patients dialogue better with their physicians about treatments and that direct consumer advertising has both a positive and a negative.

I think we also heard that our premarket review processes must continue to be a high priority for the Agency, but that we need to continue to strive to maintain our resources, conserve those resources, and use them in the most efficient and effective way.

I think we also heard that there is a question about our relationship with HCFA and the gap between FDA-approved products and those approved for payment and that, perhaps, one of our partnerships should be with HCFA to eliminate that problem.

And then I also think we heard that we need more research by culturally competent research scientists, so that we have adequate representation in studies that are brought forward to us with both minority groups and women.

I think the other overriding issue that we heard is that making trade-offs in an era of constrained resources is difficult. I don't think any of our speakers were willing to tell us how to make those trade-offs, but we are continuing to ask for your input, and we appreciate your being here very much.

I think we will now take a 20-minute break. At the end of 20 minutes, we will come back and have our second panel.

[Recess taken from 10:11 a.m. to 10:29 a.m.]

MS. SUDYAM: I'd like to ask the panelists for the next session to please come up and take their seats.

I think we are ready to get started, and we are going to change the order of this panel slightly, since I believe that Bert Spilker, who is from the PhRMA is not here yet. Susan Zagame has some overheads, so we are going to start with Susan, and the FDA panel is going to have to rearrange themselves, so that we can see the overheads.

So our first speaker this morning is Susan Zagame, who is Vice President for Technology and Regulatory Affairs for the Health Industry Manufacturers Association.

MS. ZAGAME: Good morning. Thank you, Linda. I, too, would like to thank FDA for the privilege of being able to participate in these stakeholders meetings. HIMA also participated in the CDRH-specific meeting, and we will try

not to repeat ourselves.

I think Linda made the point about what the purpose of this meeting is. We paid very close attention to the actual words in the Federal Register notice of August 20th announcing this meeting. I just wanted to point out that some of the obligations that are listed in that document are not found, per se, in the Federal Food Drug and Cosmetic Act, and this leads me to one of my first overall general points, which is that, in trying to balance its resources and use its resources wisely, we believe FDA should stick to its core statutory functions as contained in the Act. And CDRH, at its presentation, outlined 53 specific obligations under the Act that it's required to perform.

And then as a final general overall point, we just would like to say emphatically that we don't believe that user fees are the answer, at least for the device industry.

There were a list, of course, of some eight specific obligations, and we were asked to comment on them. I am not going to repeat each of those, but I will mention some of our comments.

Conducting research, we believe, is not specifically listed as an obligation under the law. The obligation for FDA is to determine whether applications meet statutory standards of safety and effectiveness or

substantial equivalence for devices, and having the expertise to be able to make those judgments is where FDA should focus its resources, not simply on the conduct of research, particularly in cases like CBER, where the review of devices is far in excess of the statutory timeframes.

The second one talks about FDA's establishing standards. Well, again, the standards for safety and effectiveness are in the law. FDA is required by FDAMA to recognize standards, and we know that they are now participating and encourage them to participate continuously in the formation of international and national consensus standards. It's a good process, and I think FDA has embraced it.

The third obligation in the Federal Register is reviewing new product applications and, of course, this is a core statutory function that FDA needs to focus its resources on. However, we just want to point out for the record that determining the product's acceptability connotes more than the statutory requirements for approval and clearance, and that's just one of those details we wanted to point out. Again, sticking to the statutory requirements is important in this context.

Assisting new product sponsors in designing and implementing research and testing protocols, again, this echoes some of the FDAMA provisions that talk about the need

for industry and FDA to collaborate and to come to a meeting of the minds early in the process as to what those testing protocols will do. We believe that's essential to meeting the time frames under the statutes because if you have a clear road map right upfront, you are going to better be able to meet those timeframes.

Determining experience with products once they are on the market. We assume that FDA means the statutory programs that are contained in the Act of postmarket surveillance, medical device reports, and so forth. Our comment on this echoes what we said at the CDRH-specific stakeholders meeting; that these processes should be improved and made more efficient, such as the use of the Sentinel System.

As far as inspections, I have combined inspections and this variety of strategies obligation. I want to make the comment here that we believe that, as far as FDA's very important role of ensuring compliance with all of the elements of GMPs and so forth, that their philosophy should be one more of helping companies come into compliance through education. And I think we've got a lot of good examples of how joint education and training of both reviewers, inspectors, and company people can really contribute to that goal. And, again, we wanted to reiterate that ISO certifications should mean something in the

inspection process and the triage process as to who FDA inspects, when, and with what frequency.

As far as educating consumers go, again, we questioned where in the statute this appears. We believe that it's important for manufacturers to include information about their products on their labeling. We believe that, as far as FDA educating consumers and health professionals on risk avoidance, comment from some of the manufacturers that I have spoken with was that risk avoidance is not totally possible in life. There is always going to be some element of risk and, perhaps, FDA could do the public a service by educating people on the realistic expectations of technology. Technology is not a panacea for everything, and it's not perfect.

With regard to the specific questions: Generally, there was a question as to which of those obligations it's appropriate for FDA to charge user fees for. We, for a number of years, have opposed user fees, believing that they are not appropriate for the device industry and that the FDAMA tools and the re-engineering tools that the Agency has so aptly adopted should be made to work.

We believe in third parties, but let the record show that HIMA does not intend to conduct any third-party reviews.

With regard to what are the appropriate areas for

third-party research. Of course, through entities like NIH, academia, and the like should be used synergistically by FDA; of course, the creation of national and international consensus standards, product reviews, insofar as the law allows it and, hopefully, that law will be able to be expanded in future years with the expected success of the third-party program; and then inspections, third-party inspections. And, again, my point here is that there are international bodies inspecting manufacturers now. Harmonization with those inspections should be the goal.

I will just go over these briefly. This was a best areas for FDA collaboration with external stakeholders. Again, some of this is fairly obvious--research, development of standards, and product reviews.

Best area for FDA emphasis on nonregulatory approaches. And, again, this has to do with education, and bringing people into compliance, and feeling there was that standards product reviews and inspections are the areas where that could be most beneficial.

The idea of an FDA sanction or an FDA seal or mark and whether user fees would be appropriate for that, we are somewhat dismayed by that because we never believed that Section 421 of FDAMA, which took away the penalty for saying that your product was in compliance with the gold standard, was not ever intended to be a cash cow for the Agency. The

section does allow the statement to be made and, obviously, if you have gotten your FDA clearance or your FDA approval, you have been determined to meet that standard, and we are a little bit confused as to what is meant by the ability of that standard or seal to encourage appropriate behavior.

So, again, we believe that there are existing mechanisms in the law that really do require companies to meet that standard.

And then, finally, in conclusion, we recommend that FDA continue to use and evolve the FDAMA and the re-engineering tools to work synergistically with industry, academia, NIH, consumer groups, and others to improve itself and to focus its activities on core statutory functions.

Thank you.

MS. SUDYAM: Thank you, Ms. Zagame. If we could ask the FDA panel to come back to the table. Are there any questions? Yes, we do have questions. Ms. Holston?

MS. HOLSTON: I need some clarification on one of the points you raised about educating the consumer. It sounded as if you were saying that we do have some core statutory responsibility to educate industry about how to comply with our requirements, but no responsibility to educate consumers about how to appropriately use the products we regulate.

MS. ZAGAME: I guess I don't know where there is,

in the statute, that specific function. I think that there certainly are many ways in which FDA can provide links to manufacturers, to professional associations, to medical societies and others, where, generally, that kind of information can be obtained. Because I do believe that the relationship between physician and patient is a sacred one and that those kinds of decisions are best left to physicians and the assiciations and others that they interact with.

MS. HOLSTON: When you are talking about, for instance, a food label, which really is a form of educating a consumer, that's a statutory requirement.

MS. ZAGAME: Right. That was brought about by the Nutritional Labeling and Education Act. That's a specific requirement.

MS. HOLSTON: So only in the narrow, you are saying that we only have a narrow responsibility to educate if there is a specific law passed to that effect?

MS. ZAGAME: Yes. That's what I am saying.

MS. SUDYAM: I think one of the--if I could make a comment--one of the objectives of 406(b) is to maximize the availability and clarity of information about new products to consumers. So I think from my perspective, that certainly hints at a statutory obligation of the Agency.

MS. ZAGAME: Yes. I agree that it hints at it,

and I think there are ways to meet that objective without engaging in a well-funded, resource-consuming attempt by the Agency to do that, such as, as I mentioned before, providing links, making consumers aware of Web sites that are available to obtain that information.

MS. SUDYAM: Other questions? Mr. Michels?

MR. MICHELS: Representing a field organization, I am particularly interested in the perspective on openness and education. I think, as you are aware, we have spent thousands of hours, in terms of meetings with industry groups and individual firms, and in changing our behaviors in terms of how we go about doing inspections, in terms of our expectations and openness. There are some that would say possibly we have gone too far. There are others that say that there are still opportunities.

Where do you believe that we are in that spectrum? Are we doing okay or do we need to keep pushing on?

MS. ZAGAME: The feedback I have been getting is that the relationships between the field and industry have been improving in a very good direction; that there is a lot of give and take, that the, for instance, preannounced inspections has been a positive element, that coming into compliance with FDA's requirements is something that is desired by industry.

Obviously, when you have such a diverse amount of

information that's required or expertise that is required of your field inspectors, it makes for challenges, and there is always room for improving the education base of inspectors, as well as industry, as far as coming into compliance.

MS. SUDYAM: Dr. Schwetz?

DR. SCHWETZ: I have a question of you about the support for research within the Agency. You said that in the area of research that's one place where we should be collaborating with stakeholders, but you also said earlier in your comments that you didn't think there was much of a place for research within the Agency, if there was any place for it. Can you expand on how we would engage in collaboration in research if we don't have researchers within the Agency.

MS. ZAGAME: Well, I guess my point there was that, if you, as a--like if CDRH determines that it needs to have some research done in polymer chemistry, for example, and it doesn't have an expert in polymer chemistry within its ranks, it ought to go ask NIH or some research institution that has that capability to work with it, either on a cooperative basis or through a contractual agreement which, again, is provided for under FDAMA, and that that kind of enhancement of your capabilities, through use of outside resources, would be the only suggestion I have there.

MS. SUDYAM: Thank you very much.

Our next speaker is Mr. Stephen Northrup, who is the Executive Director for the Medical Device Manufacturers Association.

MR. NORTHRUP: Thank you very much and good morning. My name is Steve Northrup, and I am Executive Director of MDMA, the national voice for the innovators and entrepreneurs in the medical device industry.

As you may know, MDMA was created in 1992 by a group of executives at smaller medical device companies, who believed their firms needed a distinct presence here in Washington. On behalf of our nearly 130 members, I appreciate this opportunity to appear before you today to discuss how the FDA can best meet its obligations under the Food and Drug Administration Modernization Act.

These public meetings are an excellent first step toward the development of the Agency's FDA modernization compliance plan, but we hope the Agency will continue to consult with its stakeholders throughout this process. The FDA needs to do more than offer us the opportunity to respond to open-ended questions at a few public hearings. That comment is not meant to belittle today's event. As I said earlier, this is an excellent first step. However, the Agency does have a number of tools at its disposal for continuing this dialogue and MDMA encourages the Agency to

use these tools generously.

On behalf of our members, I would like to make one general suggestion before commenting specifically on a couple of the questions at hand. If the FDA doesn't have the staffing levels it needs to carry out with distinction all of its statutory missions, then the Agency should look off-campus and leverage the resources of other organizations toward the fulfillment of the Agency's goals, and I think this speaks to the previous question. In other words, the Agency should do what all of us are doing, to some extent, and that is contract with those organizations that have the resources or the ability that we cannot afford to have on our full-time staff.

As an example, the Federal government decades ago decided not to create a gigantic Federal biomedical research enterprise and instead chose to build a public-private partnership between the Government and the nation's universities, medical schools, and teaching hospitals. Today, most of the funds appropriated to the National Institutes of Health are spent in support of the biomedical and health services research conducted at universities and academic medical centers.

The amount of intramural research conducted by NIH employees pales in comparison to the amount of high-quality, extramural research carried out under contract to the NIH.

A more recent initiative along these lines is last year's establishment by the Federal Agency for Health Care Policy and Research, or FAHCPR, of evidence-based practice centers. These Centers of Excellence, located at academic medical centers and other research organizations, conduct a variety of studies and facilitate the translation of research findings into clinical practice. Taking advantage of our nation's tremendous non-Federal research infrastructure, FAHCPR now supports a number of significant studies on an extraordinarily limited budget.

The FDA Modernization Act gives the Agency greater authority to contract with other organizations and also directs the Agency to establish a system for the third-party review of device submissions. MDMA believes the Agency's further leveraging of the resources of outside organizations would enable the Agency to stretch its budget further without compromising the quality or integrity of its science.

Turning to a couple of the specific questions at hand. MDMA strongly opposes levying user fees on device submissions, site registrations or any other aspect of the FDA's regulatory scheme for medical devices. MDMA is proud to have been one of the few groups to oppose vocally medical device user fees in 1994, when other industry representatives were supporting user fees and negotiating

their scope and parameters with Congress.

Our opposition to user fees, both then and now, is based on philosophical and practical considerations. On the philosophical level, MDMA opposes user fees as a tax on innovation and a barrier to the development of new technology. As we know, the pace of innovation in the medical device industry is driven by smaller manufacturers and particularly start-up companies.

Now, many large companies during the 1994 debate on user fees supported the concept, and this is understandable since large companies can spread the cost of user fees over the income derived from scores, not hundreds, of product lines. Small and start-up companies, however, have little or no product revenue to defray the up-front cost of user fees.

Furthermore, while the pharmaceutical industry seems generally satisfied with the Prescription Drug User Fee Act, there are several reasons why what is good for the drug industry is not good for the device industry. First, the innovative process in the device industry is iterative. Existing products are frequently modified as a result of clinical experience. As a result, patent protection means much less to medical device manufacturers than it means to pharmaceutical firms, which acquire patents for unique chemical entities.

In addition, the markets for advanced medical technology are much smaller than the markets for leaving drugs which, combined with user fees, could discourage innovations in markets of great clinical significance, but limited demand.

On the practical level, MDMA and its members have traditionally opposed user fees because of our belief that the FDA's inappropriate allocation and inefficient use of its resources, not a lack of resources, were to blame for the Agency's inability to review products in a timely manner. In our opinion, recent statistics bear this out.

Consider that with no significant increase in resources for CDRH's Device Review activities, with no decrease in total submissions received, and despite the increased complexity, as FDA says, of device submissions, average review times have fallen significantly and dramatically since Fiscal Year 1994.

The average total review time for original PMA submissions dropped from 452 days in Fiscal Year 1994 to 247 days in Fiscal Year 1997. The average total review time for PMA supplements decreased from 295 days in Fiscal Year 1994 to 112 days in Fiscal Year 1997. The average total review time for 510K submission decreased from 216 days in Fiscal Year 1994 to 130 days in Fiscal Year 1997.

Dr. Burlington, Dr. Alpert, and the staff of

CDRH's Office of Device Evaluation deserve the appreciation of the medical device industry for their diligent re-engineering and the resulting decreases in review times. These statistics that I have quoted, however, demonstrate that lengthy FDA review times did not evolve from a lack of resources.

In addition to opposing user fees, we strenuously object to the concept of charging manufacturers a fee for the use of some sort of FDA seal of approval on their products. If one manufacturer agreed to pay this fee while another manufacturer of a similar product refused to pay, a health professional or a consumer might reasonably conclude that the product with the seal was somehow more safe or more effective than the product without the seal, even though both products had met the same standards. To MDMA, this proposal is nothing more than user fees by another name.

Thanks again for the opportunity to appear before you today, and we look forward to working with the Agency and meeting the challenges and the promise of the next century.

MS. SUDYAM: Thank you, Mr. Northrup. Does anyone on the FDA panel have any questions or comments? Mr. Byrd?

MR. BYRD: One comment. We certainly appreciate the comments about CDRH and their ability to do what they have done with regard to review times with the resources

that they have had, but it should be understood that CDRH still has a tremendous need for additional resources. Being able to sustain those accomplishments is now the issue with CDRH. We have all of the FDAMA regulations to implement and the burdens put onto the Agency by FDAMA. So, even though we have done a lot, and Dr. Burlington, and Dr. Alpert, and the others at CDRH should certainly be congratulated, as you did, we should just understand that sustaining that level of effort still requires--

MR. NORTHRUP: We recognize that, and we believe that FDAMA includes some tools that the Agency did not necessarily have before and also encourages the Agency to take further advantage of its tools to leverage its resources and do what all of us have to do, and what I have to do at MDMA because we have a very small staff, which is go outside the Agency and take advantage of the resources of other organizations.

So we recognize that the Agency does still have some work to do and, hopefully, the changes that Congress made in FDAMA, some of which codify what you are already doing, will continue this trend. But as time passes, I hope you will keep us informed as to whether you are meeting those statutory requirements and able to continue, and we will certainly look forward to working with you to give you whatever tools you need in the future, in terms of us

working together with you and Congress to provide you what you need.

MS. SUDYAM: Thank you. Our next speaker is Kay Gregory, who is the Director for Regulatory Affairs at the American Association of Blood Banks.

MS. GREGORY: Good morning. I am pleased to be here today to speak on behalf of the American Association of Blood Banks. The AABB is a professional society for over 8,500 individuals involved in blood banking and transfusion medicine. We also represent more than 2,200 institutional members, including community and Red Cross Blood Collection Centers, hospital-based blood banks, and transfusion services, as they collect, process, distribute and transfuse blood and blood components and hematopoetic stem cells. Our members are responsible for virtually all of the blood collected in the country and more than 80 percent of the blood that is transfused.

For over 50 years, the AABB's highest priority has been to maintain and enhance the safety of the nation's blood supply. As a voluntary standard setting and accrediting association, the AABB works hard in a number of areas to ensure a safe, readily available blood supply. We also recognize the critical role the Food and Drug Administration plays in protecting consumer health by regulating blood products.

We believe that it is essential that the FDA and the private sector, including professional organizations such as the AABB, work together in reaching our common goal; providing American's access to a safe, available blood supply. Neither the public nor the private sector can meet this goal alone. Rather, there must be a healthy balance and interaction between these interested parties.

We commend FDA for holding its recent series of meetings, including this one, regarding FDAMA, and we welcome the opportunity to provide AABB's and the blood industry's perspective on how best to meet the objectives of the Act. Through meetings such as this, as well as valuable workshops with regulated parties, FDA has demonstrated an increased interest in communicating with the blood banking community. We are hopeful that the Agency will continue to build upon these communications to enhance patient access to needed blood-related products.

Today, FDA has heard from a wide range of interested consumer health professional and industry representative suggestions to protect consumer health. While many of us have similar or complimentary recommendations, the Agency must be careful not to treat all regulated industries identically. In developing and implementing policies relating to blood products, the unique nature of this industry must be considered. A safe,

available blood supply is clearly a national health priority. Unlike other FDA-regulated products that may reach only limited populations, blood and blood-related products are needed for an extremely broad array of therapies and large, diverse populations.

In addition, although there are relatively few types of blood-related products, the exact, same products are produced in multiple locations across the country. Moreover, many of these production locations include community blood banks and hospitals and are quite different from production facilities that are operated by manufacturers of other pharmaceuticals.

Let's talk about adequate resources. We would like to stress the need for adequate Agency resources. In order for consumers to have access to safe and effective products, the FDA must have sufficient resouces to fulfill its many responsibilities. The AABB is concerned that as members of Congress and others turn increasingly to user fees to provide needed dollars, that nonuser fee programs may be neglected and not receive necessary funding.

We do not believe that user fees are an appropriate means of funding FDA's blood-related activities. User fees may be appropriate for pharmaceutical companies willing to pay for faster license application reviews, where faster approval allows these firms to increase profits by

bringing their products to market sooner. However, as a policy matter, the AABB is convinced that user fees are inappropriate for blood collected for transfusion. The nation's blood supply is a shared resource that is available to all Americans. Blood used for transfusion is drawn from altruistic individuals and processed by not-for-profit organizations.

With regard to blood and plasma collected for further manufacture, the plasma is essentially a raw material that is used to manufacture biological products that are currently subject to user fee requirements.

We recognize that, like the rest of the Government, the FDA is under considerable fiscal pressure. One way of alleviating some of these pressures may be to increase Agency collaboration with private organizations. Experienced private entities, including professional societies and voluntary standard-setting or accrediting organizations, can provide valuable services to the Agency, often at a lesser cost than it would take for the Agency to carry out similar tasks. The AABB feels strongly that the FDA should rely, to a greater extent, on third-party standard-setting and accreditation organizations.

Since 1957, the AABb has issued standards for voluntary compliance in blood and blood component collection, processing, and transfusion. In addition, in

1991, the AABB published its first standard for the collection, processing, and transplantation of hematopoetic progenitor stem cells. AABB's standards are refined and expanded every 18 months through a deliberative process that combines elements of scientific peer review, clinical experience, expert advice, and regulatory analysis.

The AABB is pleased to note that in developing its new regulatory framework for tissue products, the FDA has expressed a desire to work with private organizations in establishing national standards for the collection and use of hematopoetic progenitor stem cells. Recognizing that voluntary organizations, such as the AABB, have considerable experience in standard setting, the Agency has proposed a system under which it will review and adopt industry-specific standards developed by professional societies.

The AABB welcomes the opportunity to participate in the public-private effort to establish standards for HPCs. We urge the FDA to engage third-party organizations in similar standard-setting endeavors for blood products.

We also believe that the best model for blood and HPC standards is one that is similar to the ISO 9000 model, which was developed by the International Organization for Standardization. Using this model, organizations can incorporate a prospective, comprehensive, quality management program into the standards writing process. We are also

attracted to this model because of its universal appeal. ISO 9000 standards are being applied now throughout Europe.

Let's talk about accreditation programs. Increased cooperation with private accrediting bodies could also help FDA become more efficient and reduce burdens on accredited facilities without compromising the public safety. The AABB accreditation program strives to improve the quality and safety of blood banking practices, including collecting, processing, testing, distributing and administering blood and blood products. The accreditation program assesses the quality and operational systems in place within AABB member facilities. The basis for assessment includes compliance with AABB standards, applicable sections of the Code of Federal Regulations, and Federal guidance documents.

This independent assessment of a facility's operations helps the facility to prepare for other inspections and serves as a valuable tool to improve both compliance and operations. Accreditation is granted for a variety of activities, including blood centers, transfusion services, and hematopoetic progenitor cell activities. As of January 1998, the AABB standards will require a facility to implement and monitor a quality program.

A Federal model for Government cooperation with third-party assessors already exists in the Health Care

Financing Administration under the Clinical Laboratory Improvement Amendments of 1988. HCFA grants deemed status to certain third-party organizations with accreditation programs that the Agency determines provides reasonable assurance that the facilities accredited by them meet or exceed the conditions required by CLIA.

HCFA has granted deemed status to AABB's accreditation program, including our new quality and operational systems assessment program. We strongly recommend that FDA consider adopting an accreditation program similar to HCFA's, allowing the Agency to take advantage of the expertise of private accrediting organizations and eliminating, unnecessarily, duplicative inspections of blood-related facilities.

In its meeting notice, FDA also asked for input regarding areas in which it should place an increased emphasis on nonregulatory activities. As a general matter, the AABB believes that the Agency should first focus its regulatory energies on areas involving the greatest risk. On the other hand, supplements for established blood products, whose risks are understood, should be subject to less Agency scrutiny than new products with unknown or greater risk.

For some time, the blood industry has had concerns about FDA's review of modifications or changes to approved

blood product license applications. The AABB is pleased that the Agency and CBER have taken steps to improve this process. As to the nonregulatory functions, the AABB urges the FDA to do more to assist manufacturers in the design and implementation of research and testing protocols. More dialogue between industry and the FDA is also needed in the area of postapproval experience with products. Industry should be encouraged to report on their experiences through implementation of simpler, easier, and nonduplicative Agency reporting mechanisms.

One possible avenue for Agency-industry communications regarding the application review and postapproval review processes is FDA workshops with industry. In the blood industry, we found those workshops to be most beneficial. During similar workshops, the FDA could provide information about specific review criteria the Agency considers in assessing product applications.

Finally, we would like to stress the importance of consumer education. The AABB believes, particularly in the area of blood-related products, that Agency efforts to educate consumers about product risk and benefits are of utmost importance. Even though blood-related products are some of the most widely used FDA-regulated products, they are also among the most misunderstood by the public. These misunderstandings have led to decreases in blood donations,

as well as some unjustified fears about risk associated with blood products.

Working with industry and professionals, the FDA should devote significant staff and resources to improving the public's understanding of the blood supply, the importance of blood donation and the role of blood-related products in improving patient health.

The AABB appreciates the opportunity to share our views regarding the FDA's role in protecting consumer health, and we look forward to continuing to work with the Agency and other interested parties to ensure that Americans have timely access to safe blood-related products.

MS. SUDYAM: Thank you, Ms. Gregory. Does anyone on the FDA panel have any comments or questions? Dr. Schwetz?

DR. SCHWETZ: This isn't specifically directed to you, but a number of the panel members this morning have recommended that there needs to be more of an emphasis on the part of the Agency to educate the public, but equally important is the length of time it takes to review new products and that consumes the same people.

Can you give us some examples of how we could leverage our resources better to emphasize the educational activities, to a greater extent, without compromising the review process?

MS. GREGORY: I don't know that I have any specific recommendations to make, but I think there are ways that you can help us; for instance, in perhaps reviewing some of our educational material to make sure that it's presented in a manner that you would think would be appropriate. I think, also, working with other agencies, like CDC and HCFA, to make sure that you are all giving out the same messages when you are giving out messages is an appropriate thing to consider.

MS. SUDYAM: Thank you very much. Our next speaker is Jacqueline Eng, who is the Vice President for Policy and Strategic Planning with the U.S. Pharmacopeia.

MS. ENG: Thank you. For the past 92 years, USP has had the responsibility to establish and maintain a set of public standards against which FDA can hold pharmaceutical manufacturers and their products accountable under the adulteration and misbranding provisions of the 1906 Pure Food and Drugs Act and all of the subsequent food and drug legislation.

The availability of USP's public standards and associated reference standards contributes significantly to enabling FDA to meet its own consumer protection responsibility. The Federal legislation that binds FDA and USP in a singularly unique public-private relationship has resulted in assurances of the quality and safety of

pharmaceuticals available in the United States and in the international marketplace.

The comments I offer today on behalf of USP forward a recommendation as to our two organizations can improve upon what already has been a remarkably effective track record of protecting the public's health, an obligation shared by both USP and FDA.

Specifically, our comments fall within the context of Objectives 6 and 7, as stated in the August 20, 1998 announcement of this meeting. Objective No. 6, in calling for approaches to help the Agency meet the Agency's consumer protection obligation, reads: "Conducting inspections to determine the state of industry compliance with FDA standards," which we interpret as encompassing the standards of the U.S. Pharmacopeia and the National Formulary.

Objective No. 7 reads: "Carrying out a variety of strategies to ensure compliance, including education, technical assistance, and more directed enforcement activities, such as warning letters, product seizures, and prosecutions."

Just as FDA has been considering the future prioritization of its resources, so has USP, and it is from our internal focus on strategies for USP's future and the resulting set of priorities that we have established that we have embarked upon a course that will help ensure that an

initial USPNF monograph is published within one year of a product's approval by FDA.

The recommendation that we would ask you to consider is fairly straightforward. We would ask that FDA work with USP to ensure that there is a proposed monograph published for public comment in Pharmacopeia Forum, USP's analog to the Federal Register within one year of FDA's approval of an NDA.

Specifically, we propose that we work together to determine a mechanism by which the Agency can provide USP with the regulatory method, specifications, and relevant packaging and labeling information that are submitted in new drug applications and other approval vehicles to expedite development of these monographs.

By regulatory methods and specifications, we mean the technical parameters of the identity, strength, purity, and quality of a drug substance or drug product together with the methods of analysis by which FDA can determine that an article complies with the standard to which the product is to have been manufactured.

It is only through collaborative commitment among FDA, USP, and the industry that we can hope to achieve this challenging goal. We believe, however, that it is in the public's best interest to improve upon current practice and, quite frankly, it is why we asked for the Agency's

assistance.

We recognize that there are issues relative to the confidentiality of proprietary information and that there may be other legal, regulatory, and perhaps resource considerations associated with the Agency conveying to USP the specifications and analytical methods associated with a specific drug or drug product. We believe, though, that these are obstacles that can be overcome and hope we can begin discussions with appropriate Agency officials on this topic in the near future.

Availability of a USPNF monograph is a concrete step the Agency can take to conduct inspections to determine the state of industry compliance with FDA standards and is a strategy that supports direct enforcement activities.

Our second thought, in relation to the Agency's stated objectives, is not so much a recommendation as it is an urgency that the Agency continue as a priority its longstanding policy of support for collaborative testing of USP reference standards that support the UPSNF monographs. As noted in a recent discussion among FDA and USP officials, it is the monograph and the monographs associated reference standard upon which the Agency must base its inspections and, when necessary, its enforcement actions.

The system of collaborative testing among USP, FDA, and an appropriate third-party laboratory has been

exceptionally successful and efficient. It provides the Agency with firsthand assurance of the authoritativeness of the USP reference standard substance upon which it may institute, if necessary, enforcement actions. This collaboration should be continued as a priority.

In addition to the contribution to the safety and quality of products in the U.S. marketplace, there also is opportunity to bolster the leadership of the United States in the global marketplace with more timely availability of a public standard. We have heard consistently through this series of public meetings insistence from FDA's stakeholders that the Agency work toward internationally harmonized standards. These same stakeholders, however, caution the Agency to be wary of proposals that would result in lowering the standards of the United States.

USP's experience with international harmonization has been that, once standards are in place in the major pharmacopeia's of the world, it is extremely difficult to accomplish the desired harmonization if that harmonization means that one country or another or one pharmacopeia or another must change to the detriment of existing products.

USP appreciates FDA's support of our efforts toward pharmacopeial harmonization and urges the Agency to continue to help identify workable solutions to these situations in which traditional methods of harmonizations

have not been successful.

USP also welcomes FDA's contribution in the identification of monographs that contribute, through new development or those that are a priority for harmonization, to assisting the Agency meet the requirements of Section 410 of FDAMA, which imposes additional requirements on the Agency regarding Mutual Recognition Agreements and global harmonization.

The more current the public standards in this country, the more able the Agency will be as it works with the Office of the U.S. Trade Representative, the Department of Commerce, and representatives of foreign governments to discuss methods and approaches that will reduce the burden of regulation and will harmonize regulatory requirements consistent with FDA's consumer protection responsibility.

In closing, I want to note one final area that FDA should continue to consider a top priority. As you begin the major task of prioritizing and reprioritizing programs, projects, and personnel, we would add our voices to those you have heard throughout these public meetings that have encouraged ongoing and, indeed, more interaction, and collaboration with, and reliance upon your stakeholder communities.

USP is particularly grateful for the Agency's support that has enabled its personnel to actively

participate in USP as members of our convention, the committee of revision, and its ad hoc reviewers. In addition, the value of open, honest, and direct exchange of expertise and perspectives across staffs on issues associated with standards, information, and practitioner experience is inestimatable.

Thank you. I appreciate this opportunity to participate in this public comment process. You have a considerable task before you. My USP colleagues and I look forward to continuing our work with you to ensure the highest standards for health care products used by well-informed practitioners, patients, and consumers.

Thank you, again.

MS. SUDYAM: Thank you. Are there any questions. Mr. Michels?

MR. MICHELS: Well, first of all, thank you for your kind words on what we are doing. In terms of international harmonization of public standards, is there yet another opportunity for the Agency to be a player or, in your view, is what is in play at the moment satisfactory for the foreseeable future? Is there something else we should be doing to encourage movement in the right direction here?

MS. ENG: I think our discussions within USP, to date--and, Mr. Michels, I can't think of anything in specific at the moment--but my recollection of our internal

discussions has been that greater discussion among the affected parties from within the United States, that would certainly include PhRMA, and the other groups, and the Agency, and USP, we believe very strongly that there are ways that we can work together.

We each have our own responsibility, and we each have our own groups that we have to work with, but there are likely priorities within each of us that there is a synergy, and it is working together, as opposed to I think we still are working individually. So I think it's a synergy and sit-down, perhaps, in the right groups to talk.

MS. SUDYAM: Other comments or questions?

[No response.]

MS. SUDYAM: Thank you very much. Our next speaker is Mr. Andrew Lee, who is Program Director for The Angiogensis Foundation.

MR. LEE: Good morning. My name is Andrew J. Lee, and I am representing The Angiogenesis Foundation, a nonprofit organization that is actively working with three of FDA's external stakeholders--patients, physicians, and industry--to speed development of angiogenesis-based therapies. Our mission is important because future drugs that control angiogenesis or new blood vessel growth have the potential for treating 497 million disease cases annually, including cancer, heart disease, stroke,

blindness, arthritis, and psoriasis.

In the 21st Century, new treatments for these conditions will come from molecular medicine, and the FDA will face new challenges created by molecular medicine. In this regard, The Angiogenesis Foundation has identified three areas that merit the FDA's particular consideration with regard to FDAMA.

First, in an era of molecular medicine, the FDA must rely upon third parties for objectivity, expertise, and information because as scientific discoveries become the driving force for new therapeutics, it is unreasonable to expect the FDA to independently master all of the complex scientific specialties and to independently understand the full scope of risks and benefits related to these emerging technologies.

For example, the field of angiogenesis is scatter across more than 25 scientific and medical disciplines, including cardiology, dermatology, gynecology, oncology, opthalmology, rheumatology, and AIDS medicine. Over 200 new scientific papers on angiogenesis are published monthly in peer-reviewed journals. More than 200 biopharmaceutical companies, spanning more than four continents, are developing angiogenesis-based drugs. There have been two dozen scientific meetings in 1998 discussing angiogenesis alone. To assess the therapeutic contributions of all of

these activities, The Angiogenesis Foundation analyzes information from 53,500 sources in 13,500 databases weekly using a team of scientific, medical, and business analysts.

Given the resource constraints within which FDA must operate, the Agency should rely upon and collaborate with external institutions such as ours for relevant information. Working with nongovernment organizations will prevent the costly duplication of efforts already underway in the private sector.

Second, in an era of molecular medicine, FDA should provide incentives encouraging pharmaceutical companies to update the knowledge base of health care providers. Molecular medicine is based upon rapidly involving scientific information, and there is an increasing knowledge gap between what physicians were taught in medical school and what they need to know today to apply molecular drugs safely and effectively.

For example, the concept of angiogenesis is still not widely taught in U.S. medical schools, yet the first angiogenesis-based wound healing gel was approved last December and is now available for doctors to prescribe to their patients.

Based on information that The Angiogenesis Foundation provided to Time magazine in a May interview, more patient consumers know about this product than do

physicians. When patients know more about the existence of new molecular medicines than their doctor, it means there is a disturbing knowledge gap that can have an impact on consumer safety. We believe the FDA, the pharmaceutical industry, medical institutions, and private private organizations, such as ours, all share the responsibility for improving practitioner knowledge.

Third, the era of molecular medicine is also the era of technology globalization, and the FDA should continue devoting resources towards international harmonization efforts. Given the burgeoning worldwide biotechnology industry, the 21st Century may find Americans seeking effective new biotechnologies from abroad. The Angiogenesis Foundation applauds completion of the first phase of ICH and encourages further collaboration with the EU and Japan to increase harmonization of global standards.

In our therapeutic area, Canada, Great Britain, Italy, Germany, Japan, and Australia are all working on highly promising angiogenesis-based drugs. The FDA can help by contributing the American gold standard to the international phramaceutical standards. Ultimately, it will be the American consumer who benefits from the efficient review and approval of innovative drugs developed abroad.

In summary, the modernized FDA should meet the challenges of molecular medicine by collaborating with

knowledge-based external organizations as a way to amplify its information resources by guiding the phramaceutical industry towards improved knowledge base of the U.S. health care providers and by continuing cooperation with the international community to develop regulatory guidelines that will help make the best new drugs originating outside the U.S. available to the American consumer.

In all three initiatives, The Angiogenesis Foundation is willing to work with the FDA and its centers to achieve these important goals.

Thank you very much.

MS. SUDYAM: Thank you, Mr. Lee. Are there any questions for Mr. Lee from the panel? Dr. Schwetz?

DR. SCHWETZ: In some ways, the medical school curriculum is a bit like the FDA, they are both saturated with things, and there aren't any vacant times or vacant people to introduce a lot of new information to be taught to medical students.

Do you think that the knowledge that the public has about new products here will drive the physicians to gain more information and to ask for more information in the medical school curriculum or is that something that the FDA should be working with medical schools to try to prioritize the topics that should be in their curriculum?

MR. LEE: Right. Well, I'll expand on something

I've already alluded to, where the existence of this topical wound-healing product was unknown, and we received calls--hundreds of calls--from patients who had read about it in Time magazine and doctors who had read about it in Time magazine who, disturbingly enough, had their only source of information about this through Time magazine.

The Angiogenesis Foundation is working extensively to try and improve this by encouraging pharmaceutical industry groups, as I mentioned in our speech as a suggestion for you all, we are already doing that, and additionally we believe, in the spirit of not draining FDA resources, that we are pushing members of our board, who do serve on medical school panels all over the world, from Athens, to Boston, to Los Angeles, to drive forward this mission. We have multiple continuing education programs that we run and, additionally, speak at grand rounds at medical colleges all over the United States on a regular basis in an effort to alleviate this problem.

So we don't want to bring a situation of placing an added burden on the FDA. We want to demonstrate that we believe a private group can sufficiently take the public interest to heart and help to improve the public knowledge and health without adding an onus on you all.

MS. SUDYAM: Thank you very much. Our final speaker for this panel is Dr. Bert Spilker, who is Senior

Vice President for Scientific and Regulatory Affairs, PhRMA. Dr. Spilker?

DR. SPILKER: Thank you, Linda. Good morning.

The FDA, like any organization, has limited resources, and those resources are already stretched to their fullest by the Agency's existing obligations and current activities. For this reason, PhRMA urges the FDA to give thorough consideration to any new functions or additional activities relating to existing functions that they wish to adopt and to avoid taking on additional responsibilities unless they contribute significantly to the Agency's statutory mission. Indeed, PhRMA commends the Agency for undertaking this public discussion of its objectives and functions and urges similar public discussion before FDA takes on any new tasks not mandated by Congress. PhRMA is commenting this morning on only three of the issues that were identified within FDA's notice of this meeting.

First, on consumer information. PhRMA believes that FDA should not undertake any activities related to Objective 2, "Maximizing the availability and clarity of information for consumers and patients concerning new products," because these activities are not sufficiently related to FDA's core missions relating to drugs, promptly and efficiently reviewing new drug applications, and ensuring drugs are safe and effective, as well as the other

missions. Thus, PhRMA urges FDA to continue to support the voluntary system to provide written information to consumers about specific prescription drugs when consumers fill new prescriptions.

FDA's role in such a system is only to "audit" the existing voluntary system by first periodically conducting a consumer survey to determine the percentage of consumers receiving written information and, second, periodically reviewing written materials to assess their quality.

The second point: Delegation to third parties. PhRMA believes that, under appropriate conditions, FDA should rely on third parties, such as private standard-setting organizations to establish standards applicable to FDA-regulated products. For example, the United States Pharmacopeia establishes voluntary standards for purity of drug products and ingredients. Such reliance on third parties would free FDA resources for tasks that cannot appropriately be delegated to third parties.

Some tasks cannot appropriately be delegated to third parties for a variety of reasons. PhRMA opposes, for example, third-party inspections of manufacturer compliance with good manufacturing practices because of the need of a single set of standards in a wide variety of settings and the ability of manufacturers to appeal directly and speedily within FDA from adverse decisions by inspectors.

PhRMA urges FDA to consider other tasks that can be delegated to third parties for some portion or all of the task. For example, delegation to third parties of some of the tasks involved in review of information for efficacy supplements is very reasonable for products that are already approved, where safety is not an issue.

The third point: Collaboration with regulated industry. There are a variety of management issues specifically not related to individual product review on which FDA could benefit from collaboration with the regulated industry. The ongoing FDA industry project on information technology is one model of such collaboration. In that project, FDA has formed an Information Management Advisory Board that will oversee the investment of PDUFA II funds toward the achievement of the information management goals of FDAMA.

PhRMA has also formed a committee, the Information Management Working Group, that mirrors and compliments the FDA's group. The FDA Board nad PhRMA working group are currently developing common goals for a common electronic information environment and a five-year information management plan to track achievement of PDUFA II goals.

There are many other models that could also be used productively to enable FDA and its various stakeholders to benefit from the sharing of managerial and operational

experiences. PhRMA is willing to work with both the central administration and the centers of FDA to provide industry knowledge that can be combined with agency perspectives that would improve the efficient administration of appropriate FDA functions.

Thank you for your attention.

MS. SUDYAM: Thank you, Dr. Spilker. Are there any questions for Dr. Spilker from the FDA panel? Mr. Michels?

MR. MICHELS: Yes. I am going to explore for a couple of minutes the issue of third-party inspections. If I heard you correctly, your sense was or the association's sense is that we are not sufficiently consistent in terms of the existing program; that is, FDA investigators, to consider a third party and engaging others in the processd. Did I hear you correctly on that point?

DR. SPILKER: No. Actually, we are saying we like the FDA having one consistent standards. We are concerned that if you hire contractors that they may not apply the rules consistently, that you may--I couldn't say if you would have more than one contractor--but, still, they would not have the experience to go out and to apply rules consistently, and especially if you had more than a single contractor. But even then, any discussions we would want to have would have to go through them, you would have to

interpret and hear their comments, and then it really just creates a lot more complications.

DR. MICHELS: Okay. I think I understand the point. Thank you.

Could I then extend the issue to our overseas counterparts? Following that same line of assumptions, you would be more comfortable in FDA investigators traveling to PhRMA facilities overseas rather than having our counterpart officials performing those inspections and providing reports to us, is that a logical extension or not?

DR. SPILER: Well, the extension has a certain logic. It certainly is not what I have said. However, the foreign inspections raise other complications. There are inspections of new drugs and the facilities that both manufacture and produce the final products if they are overseas, and I think we are certainly in favor of that, and I don't believe that that is as taxing to the FDA resources as the inspections of all of the bulk manufacturers and others that are providing ongoing products, where you are unable to get to those manufacturers on a basis that you are comfortable with.

DR. MICHELS: Thank you.

MS. SUDYAM: Ms. Holston, did you have a question?

MS. HOLSTON: No. I am sorry. My question also pertained to the relationship between what you said about

opposition to third parties and our Mutual Recognition Agreement with the European Union, as far as pharmaceutical GMP inspections, and I am still not clear because you have historically supported that. Could you clarify, again, the distinction you see.

DR. SPILKER: The first distinction that I made was between investigational and marketed products. We also do support the mutual recognition in Europe, but believe that a pilot program is appropriate, should be evaluated, and then determine whether or not it could be expanded to other regions of the world. We certainly realize you cannot just, tomorrow, just accept, by mutual recognition, anything said even within Europe, that there has to be a time to explore this, work out pilots, and we do support your taking the steps to move forward in that direction.

MS. SUDYAM: Thank you. I think this is the time when we would like to ask for comments from the floor, and I would ask the panelists to please stay in place in case there are some questions for any one of you, as well as from the FDA panel. If you would, use the microphone and identify yourself and the organization that you represent.

MR. BARG: Good morning. My name is Robert Barg. I am Vice President of Legal and Regulatory Affairs for IFLOW Corporation.

A couple of my comments are specific to areas of

user fees. I work in an area of the United States that has probably about 600 to 1,000 medical device firms in a very, very small local area. Southern California is an incubator environment. The majority of those firms are between two and ten people. User fees would cripple those companies from operating and innovation would be stifled completely.

When we look at the problems that have occurred over the time period from, say, 1993 to 1998, in a submission I put forth in about 1994, it took 584 days for that submission to go through. It was a 510(k) for a product that we had had on the market since 1990. The review time was untolerable for a small company. This year, in a period of 110 days, we got a similar 510(k) through. The ability, without user fees, is still there.

When we look at the problems that affect our industry, specifically medical devices, we need to look to where the FDA can best spend their time and money, and that is with statutory areas. Do not enter into areas that aren't set out by Congress, don't open new areas because you are spending money you don't have--specifically, research. There are universities and private concerns that can handle the research needs, and if FDA needs to go off-site for it, so be it.

When we come to the areas of selling the FDA, specifically a gold seal, I come to a problem. As an

attorney, if I put a gold seal on it--we have already heard from the FDA on preemption issues, they don't support the marketplace with preemption from local state laws--this gold seal would provide an extreme area of concern to me as an attorney as to what it really means. Is the manufacturer protected from the preemption issues? Does a 510(k) gather anything? If you don't put it on a product, are you at risk of having marketing issues?

The FDA, within FDAMA, has already been told that we are going to be able to state that the product is approved by the FDA or granted marketing authority. Selling of this gold seal seems like it is going to be a problem. Towards standards and the FDA's working with standards, the FDA needs to be a player in the area of standards. Whether they are creating them themselves or not is an issue. The FDA should be a working member on technical committees as appropriate and, where not appropriate, they should look to see whether or not that standard is something the FDA should work with.

The more the FDA buys into the standards, the better submissions will be, the faster they will go through the system, and the better the American population will be for health products.

Lastly, when it comes to issues specific to education, the panel members, both this morning and this

afternoon, have varied on what should happen. The FDA shouldn't be involved in education. That is something manufacturers have a responsibility for. That is an area that different foundations, different lobbying groups can join an effort with. I don't know that it makes a lot of sense to set up a bureaucracy for the education, where we sell the product, we have the most knowledge about it, and where we can be the most helpful towards the other stakeholders when it comes to working on our types of products. Setting up a new area in the FDA to carry that function out is a mistake.

Lastly, I want to congratulate the FDA on at least that in the last 25 years that I have worked with industries, this is now an era where we have entered into teamwork. Mr. Michels' questions are how is the field working? The field is coming together very nicely. I work out of the L.A. district office. It is a very progressive area. We have grassroots organizations that are getting together and working together on different projects that cost the FDA little or no money to have operating.

The more that the FDA looks towards industry groups where we are willing to help and add a flavor and not take away from other stakeholders, I think the FDA should make time available. It is within the FDA's purview to decide who they want to work with, but when you have

volunteers out there willing to help, I think it would be in the FDA's best interest to utilize those volunteers.

Thank you.

MS. SUDYAM: Thank you very much for your comments.

Ms. Locke?

MS. LOCKE: Rosemary Locke, again, from Why Me National Breast Cancer Organization.

I want to speak to the issue of consumer information. I am in disagreement, basically, with the last panel. Clearly, consumers recognize the limited resources of FDA, and we also want to maximize your ability toi approve safe and effective products, but I think you also have the obligation of monitoring very closely the information given to consumers about these products.

You also have an obligation to continue with products that are already out on the market, and I find myself in a somewhat unusual position because Why Me has been a leader in keeping breast implants on the market. We even have a citizen petition to the FDA to make gel available for women with breast reconstruction.

I don't want to spend a lot of time bashing or rehashing the players in the implant issue. Clearly, there is enough blame to go around--manufacturers, plastic surgeons, FDA, and consumers themselves. But you have a

particular problem when you have products that were manufactured by a number of companies. The companies either went out of business, you have trial attorneys, you have sensationalized media reports. Where are consumers and, in this case, women to get unbiased information?

Why Me, as well as those who opposed breast implants, worked with FDA to get out a breast implant brochure. And until the Institute of Medicine reports out on breast implants, consumers feel the best, most unbiased information is coming from FDA. Now, clearly, there are probably other products on the market that could fall into that category. So, while I agree that the basic responsibility lies with the manufacturer or the company, there are instances when FDA's information for consumers is invaluable.

I think that one way--oh, also, the workshops, the speaker from the Blood Bank spoke of the helpfulness of the FDA workshops and, clearly, in women's health, FDA has had numerous workshops of great value to us. So please keep up the consumer information.

MS. SUDYAM: Thank you. Thank you, Ms. Locke.

Are there any other speakers from the floor?

MR. BRADLEY: My name is Bill Bradley. I am with the Nonprescription Drug Manufacturers Association. Just to clarify, you have heard this morning from NBNA and MDMA, and

we are NDMA.

I would like to commend the Agency on these stakeholder meetings. I think they have been well-conducted. They have been very open. They have been receptive to viewpoints from many angles, and I think they pointed out the vast wealth of information and expertise that is available outside the Agency in industry and from health professionals, consumer organizations, and others.

I would like to encourage, as some others have, the Agency to not stop these open-process deliberations just because this particular series of meetings is over. But in the development of guidances, in the development of regulations, I think that, in this time of diminishing resources of the Agency, it would do very well to continue the open process, to utilize these many resources that are available to it on a voluntary basis, and I think the result will be quicker development of regulations and guidances. It will result in greater compliance, easier compliance. It will result in more reasonable regulations. And I think that everyone, including the consumers that use these products, will benefit.

MS. SUDYAM: Thank you. Are there any other comments from our panelists or from the FDA listening group?

[No response.]

MS. SUDYAM: I think would like to summarize,

briefly, what I heard from the last panel.

I think, first, very strongly, a number of the speakers spoke to FDA sticking to its statutory obligations and not to take on new obligations if they are not specifically required under the law. I think there was a very strong difference of opinion about the role of FDA and the value of consumer education in improving health outcomes.

I think we heard a lot of people's views that education is not FDA's role, and I think we also heard that education from an unbiased group would be important to a lot of consumers.

I think we also heard that collaboration with our stakeholders is a process that is essential to the healthy functioning of the FDA and that it will help us to meet our statutory obligations in a more efficient way. I think we have some notable examples of things that have worked well in the past, including the USP drug monographs and, obviously, the international harmonization activities.

I think many people spoke to their appreciation to be able to participate in this process, and they look forward to ongoing collaboration in the future, and I would like to make the point now that we do consider this to be an ongoing process and intend to continue with stakeholder meetings and expect that we will hold the next round of

those in the spring.

I think we also heard that the Agency needs adequate resources to do its job. And the real question is what is the level of adequate resources, and can we continue to reengineer to improve review times without additional resources. I think that is a question that is one that we are struggling with, that we are all struggling with.

I think we also heard from many people on the panel that user fees are not appropriate and are not supported by the industry; specifically, the medical device manufacturers in both HIMA and MDMA and, also, in the blood banking industry.

I think we also heard that FDA needs to leverage its resources and can do that by utilizing expertise that exists in other organizations, both within the government and within the academic community as well.

And I think, also, we recognize the importance of third parties, but it is questionable exactly what level third parties should be included in the FDA process. But they can be effective in some of our regulatory activities.

And I think the comment on the FDA seal was specifically that most people weren't sure how that might be utilized.

As we look for alternative mechanisms of getting FDA's job done, I think we want to explore all possible

alternatives, and we appreciate the opportunity that we have had to listen to all of you today, and we look forward to your continued involvement in this process and to your continued involvement in helping FDA meet its statutory obligations.

Thank you all very much for attending today. Please give us your comments to the docket, if you have additional information.

[Whereupon, at 11:55 a.m., the proceedings were adjourned.]

- - -

CERTIFICATE

I, **THOMAS C. BITSKO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

THOMAS C. BITSKO